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EXAMINER	
STEELE, AMBER D	

ART UNIT	PAPER NUMBER
1639	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/586,045	SOHN ET AL.	
	Examiner	Art Unit	
	AMBER D. STEELE	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 April 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *18-71* is/are pending in the application.

4a) Of the above claim(s) *21, 24, 35-37, and 39-71* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *18-20, 22, 23, 25-34, and 38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *July 14, 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

1. Claims 1-17 were originally filed on July 14, 2006.

The preliminary amendment received on July 14, 2006 canceled claims 1-17 and added new claims 18-71.

The amendment to the claims received on April 16, 2010 amended claims 18, 28, 29, and 38.

Claims 18-71 are currently pending.

Claims 18-20, 22, 23, 25-34, and 38 are currently under consideration.

Election/Restrictions

2. Applicants elected, with traverse, Group I (claims 18-38) in the reply filed on September 8, 2009. Claims 39-71 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions, there being no allowable generic or linking claim.

3. Applicants elected, with traverse, human IL-2 as the species of target protein, yeast genomic DNA as the species of source and type of polynucleotide, *S. cerevisiae* as the species of cell, invertase as the species of reporter, and automatic screening vector comprising Gal10 promoter as the species of screening vector in the reply filed on September 8, 2009. Claims 21, 24, and 35-37 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected species, there being no allowable generic or linking claim.

Priority

4. The present application claims status as a National Stage (371) of PCT/KR04/03517 filed December 30, 2004. The present application also claims foreign priority to KR 10-2004-0003610 filed January 17, 2004 and KR 10-2004-0003957 filed January 19, 2004.

5. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file. Translations for KR 10-2004-0003610 and KR 10-2004-0003957 were provided in the response filed on April 16, 2010.

Specification

6. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

New Objections

Claim Objections

7. Claim 38 is objected to because of the following informalities: TFP should be defined in the preamble (i.e. see preamble of present claim 18) and "mutant strain yeast" in method step (e) should read "yeast mutant strain" for consistency between the method steps. Appropriate correction is required.

Withdrawn Rejections

8. The rejection of claims 18-20, 22, 23, 25-34, and 38 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject

matter which applicant regards as the invention is withdrawn in view of the claim amendments received on April 16, 2010.

9. The rejection of claims 18, 19, 23, 25, 28-33, and 38 under 35 U.S.C. 102(b) as being anticipated by Baker et al. U.S. Patent 6,136,569 issued October 24, 2000 is withdrawn in view of the claim amendments received on April 16, 2010.

10. The rejection of claims 18, 19, 23, 25, 28-33, and 38 under 35 U.S.C. 102(b) as being anticipated by Baker et al. WO 99/49028 published September 30, 1999 (provided by applicants in the IDS) is withdrawn in view of the claim amendments received on April 16, 2010.

11. The rejection of claims 18-20, 22, 23, 25-34, and 38 under 35 U.S.C. 103(a) as being unpatentable over Baker et al. U.S. Patent 6,136,569 issued October 24, 2000; Baker et al. U.S. Patent 5,212,058 issued May 18, 1993; and Black et al. U.S. Patent 5,547,871 issued August 20, 1996 is withdrawn in view of the claim amendments received on April 16, 2010.

12. The rejection of claims 18-20, 22, 23, 25-34, and 38 under 35 U.S.C. 103(a) as being unpatentable over Baker et al. WO 99/49028 published September 30, 1999 (provided by applicants in the IDS); Baker et al. U.S. Patent 5,212,058 issued May 18, 1993; and Chung et al. U.S. Patent 5,712,113 issued January 27, 1998 is withdrawn in view of the claim amendments received on April 16, 2010.

New Rejections Necessitated by Amendment

Claim Rejections - 35 USC § 112

13. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

14. Claims 18-20, 22-23, 25-34, and 38 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a **new matter** rejection. Support for the limitation "one **or more** of said plurality of polynucleotide fragments comprises said TFP" (emphasis added) was not found in the originally filed specification. While applicants point to various parts of the specification for support, support was not found for more than one TFP linked to a single vector (see method step b of claims 18 and 38).

15. Claims 18-20, 22-23, 25-34, and 38 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant is directed to the Guidelines for the Examination of Patent Applications under the 35 USC 112, first paragraph "Written Description" requirement, Federal

Register, Vol. 66, No. 4 pages 1099-1111, Friday January 5, 2001. This is a **written description** rejection.

Claims 18 and 38 are drawn to a method for identifying a translational fusion partner (TFP) capable of stimulating secretion of a target protein which is poorly secreted by recombinant production, the method comprising (a) preparing an automatic screening vector comprising a polynucleotide encoding a fusion polypeptide that comprises said target protein linked to a reporter protein (i.e. invertase), (b) linking a plurality of polynucleotide fragments to said automatic screening vector to create a library wherein one or more of said plurality of polynucleotide fragments comprises said TFP which is capable of inducing secretion of said fusion polypeptide, (c) transforming said library into host cells (i.e. a yeast mutant strain) having no activity of said reporter protein prior to transformation, (d) culturing said host cells (i.e. yeast mutant strain on a medium containing only sucrose as a carbon source), and (e) identifying said TFP by detecting activity of said reporter protein (i.e. invertase) which is secreted from one or more of said host cells (i.e. yeast mutant strain) and variations thereof. The invention as claimed encompasses all known TFPs (i.e. translational fusion partner) and all potential TFPs since various polynucleotides are "capable of inducing secretion" (i.e. encoding a chaperone, encoding a signal sequence, encoding a modulator of translation, etc.). The claimed invention states that the TFP "is capable of inducing secretion of said fusion polypeptide" and that the TFP can be a fragment. The claimed invention does not include any structural information regarding how the TFP induces secretion of said fusion polypeptide (i.e. which fragment of the TFP is critical for secretion). In addition, the claimed invention does not include any structural information

regarding how a polynucleotide (i.e. one or more is a TFP) or polynucleotide fragment can be capable of inducing secretion of said fusion protein in any host cells.

The specification teaches four TFPs that are specific for yeast (i.e. TFP1, 2, 3, and 4 or SEQ ID NOs: 2, 4, 6, and 8 for the polynucleotide and SEQ ID NOs: 1, 3, 5, and 7 for the polypeptides; please refer to page 23 and the sequence listing). TFP1, 2, 3, and 4 do not share significant sequence identity and the specification does not teach a core structure necessary for "inducing secretion of said fusion polypeptide" in any host cell. In addition, the claimed invention does not include any structural information regarding the TFP. Furthermore, the specification does not teach how TFP1, 2, 3, or 4 can induce secretion of said fusion proteins in cells other than yeast Therefore, one skilled in the relevant art would not reasonably conclude that the Applicants had possession of the invention as claimed since the structural limitations for the TFP is not included in the claimed invention.

See Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was *in possession of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See page 1116.).

With the exception of TFPs 1, 2, 3, and 4 as disclosed by the specification, the skilled artisan cannot envision the method of claims 18 or 38. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V.

Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class wherein the specification provided only the bovine sequence.

Additionally, Cf. University of Rochester v G.D. Searle & Co., Inc., Monsanto Company, Pharmacia Corporation, and Pfizer Inc., No. 03-1304, 2004 WL 260813 (Fed. Cir., Feb. 13, 2004) held that:

Regardless whether a compound is claimed per se or a method is claimed that entails the use of the compound, the inventor cannot lay claim to that subject matter unless he can provide a description of the compound sufficient to distinguish infringing compounds from non-infringing compounds, or infringing methods from non-infringing methods.

Furthermore, Ariad Pharmaceuticals Inc. v. Eli Lilly & Co., 94 USPQ2d 1161 (Fed. Cir. 2010) held that:

Written description requirement ensures that, if a chemical or biotechnology patent claims a genus by its function or result, the specification recites sufficient materials to accomplish that function; without the written description requirement, claims that merely recite a description of a problem to be solved while claiming all solutions to it would cover any compound later actually invented and determined to fall within claim's functional boundaries, leaving it to pharmaceutical industry to complete an unfinished invention. Written description doctrine must be applied even though it may disadvantage universities to the extent that basic research cannot be patented, since patent law has always been directed to "useful Arts," meaning inventions with practical use, since universities may not have resources or inclination to work out practical implications of basic research into scientific principles and mechanisms of

action, and since requiring written description of invention properly limits patent protection to those who actually conceive of complete and final invention with all its claimed limitations, and disclose fruits of that effort to the public; although fact that research hypotheses do not qualify for patent protection may result in some loss of incentive, claims to research plans also impose costs on "downstream" research, discouraging later invention, and written description doctrine sets correct balance by giving incentive to actual invention rather than attempts to "preempt the future before it has arrived." Much university research relates to basic research, including research into scientific principles and mechanisms of action, *see, e.g., Rochester*, 358 F.3d 916, and universities may not have the resources or inclination to work out the practical implications of all such research, *i.e.*, finding and identifying compounds able to affect the mechanism discovered. That is no failure of the law's interpretation, but its intention. Patents are not awarded for academic theories, no matter how groundbreaking or necessary to the later patentable inventions of others. "[A] patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion." *Id.* at 930 n.10 (quoting *Brenner*, 383 U.S. at 536). Requiring a written description of the invention limits patent protection to those who actually perform the difficult work of "invention"—that is, conceive of the complete and final invention with all its claimed limitations—and disclose the fruits of that effort to the public.

16. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

17. Claims 18-20, 22-23, 25-34, and 38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. One of skill in the art would not be able to determine the scope of the presently claimed invention. For example, the metes and bounds of "which is poorly secreted by recombinant production" is not clear (i.e. in relation to what, what specific level of secretion is considered "poor", etc.).

Claim Rejections - 35 USC § 102

18. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

19. Claims 18-20, 22, 25, 28-33, and 38 are rejected under 35 U.S.C. 102(b) as being anticipated by Jacobs U.S. Patent 5,536,637 issued July 16, 1996.

For present claims 18-20, 22, 25, 28-33, and 38, Jacobs teaches methods comprising linking a signal sequence (i.e. TFP), a target protein including cytokines, specifically G-CSF, and a reporter protein including invertase in a vector to create a library; transforming the library into host cells including yeast, specifically *Saccharomyces cerevisiae*; culturing the host cells including growth on medium wherein sucrose is the only carbon source; selecting yeast cells capable of growth on sucrose; and purification and analysis of the signal sequence and target protein (please refer to the entire specification particularly columns 1-6).

Therefore, the teachings of Jacobs anticipate the presently claimed method.

Claim Rejections – 35 USC § 103

20. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

21. Claims 18-20, 22-23, 25-34, and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jacobs U.S. Patent 5,536,637 issued July 16, 1996; Baker et al. WO 99/49028 published September 30, 1999 (provided by applicants in the IDS); and Chung et al. U.S. Patent 5,712,113 issued January 27, 1998.

For present claims 18-20, 22, 25, 28-33, and 38, Jacobs teaches methods comprising linking a signal sequence (i.e. TFP), a target protein including cytokines, specifically G-CSF, and a reporter protein including invertase in a vector to create a library; transforming the library into host cells including yeast, specifically *Saccharomyces cerevisiae*; culturing the host cells including growth on medium wherein sucrose is the only carbon source; selecting yeast cells capable of growth on sucrose; and purification and analysis of the signal sequence and target protein (please refer to the entire specification particularly columns 1-6).

However, Jacobs et al. does not teach gDNA from yeast including *Saccharomyces* (regarding the TFP).

For present claims 18-20, 23, 25-33, and 38, Baker et al. teach methods comprising preparing vectors via fusing a reporter gene (i.e. encoding a reporter protein) including invertase or amylase with signal sequences including genomic DNA fragments comprising signal sequences from *S. cerevisiae*, transforming the vectors into *S. cerevisiae* which do not have

active reporter genes, culturing cells including culturing cells on media containing only sucrose as a carbon source (i.e. for invertase) or starch (i.e. for amylase), identifying reporter protein activity, and isolating secreted polypeptides encoded by the polynucleotide fragments (please refer to the entire specification particularly the abstract; Figures 1-3; pages 1-4, 6-13, 16, 17).

However, neither Jacobs nor Baker et al. teach the Gal10 promoter.

For present claims 20, 22, and 34, Chung et al. teach methods of making fusion proteins including utilizing human IL-2 and Gal10 promoters (please refer to the entire specification particularly the abstract; Figures 1, 5, and 6; columns 3 and 5).

The claims would have been obvious because the substitution of one known element (i.e. cDNA, genus of promoter, and genus secretion signals, genus of fusion polypeptides as taught by Jacobs) for another (i.e. species of yeast gDNA library and species of Gal10 promoter taught by Baker et al. and species of human IL-2 and species of Gal10 promoter taught by Chung et al.) would have yielded predictable results (i.e. screening for secreted polypeptides in yeast via an invertase reporter system utilizing TFP from a specific source, polypeptide expression in yeast via Gal10 promoter in vectors, etc.) to one of ordinary skill in the art at the time of the invention. See *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385 (U.S. 2007).

Double Patenting

22. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re*

Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

23. Claims 18-20, 22, 23, 25-34, and 38 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4, 11-17, 21-25, 33-35, 39-42, 45-47, 50-51, 54-55, 72, 74, 76-80, 86, 91, 97, 100, 105, 109, 114, 117, and 119 of copending Application No. 11/914,437. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the presently claimed methods and the methods as claimed in 11/914,437 are drawn to methods of identifying a TFP.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Arguments and Response

24. Applicants' arguments directed to the rejection on the ground of nonstatutory obviousness-type double patenting as being unpatentable over 11/914,437 for claims 18-20, 22, 23, 25-34, and 38 were considered but are not persuasive for the following reasons.

Applicants request that the rejection be held in abeyance.

Applicants' arguments are not convincing since the claimed invention of 11/914,437 renders obvious the method of the instant claims. In addition, while a request may be made that objections or requirements as to form not necessary to further consideration of the claims be held

in abeyance until allowable subject matter is indicated, the present is a rejection and will not be held in abeyance (see MPEP § 714.02).

Conclusion

25. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Future Communications

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AMBER D. STEELE whose telephone number is (571)272-5538. The examiner can normally be reached on Monday through Friday 9:00AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Amber D. Steele/
Primary Examiner, Art Unit 1639